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Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before Friday, September 16, 2011. Oral presentations from the public will be scheduled between approximately 2 p.m. and 3 p.m. on Friday, September 23, 2011. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before Friday, September 2, 2011. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by Tuesday, September 6, 2011.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please notify Walter Ellenberg at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 28, 2011.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Eligibility Criteria for Sites Recruiting National Health Service Corps Scholars

AGENCY: Health Resources and Services Administration, HHS.

ACTION: General notice.

SUMMARY: The Health Resources and Services Administration (HRSA) announces the eligibility criteria, including their Health Professional Shortage Area (HPSA) scores, for entities that are seeking to recruit National Health Service Corps (NHSC) scholarship recipients (Corps Personnel, Corps members) during the period July 1, 2011, through June 30, 2012. A searchable database that specifies all currently approved NHSC service sites is posted on the NHSC Web site at <http://datawarehouse.hrsa.gov/HGDW/Reports/OneClickRptFilter.aspx?rptName=NHSCAppSiteList&rptFormat=HTML3.2>. This database can be searched by State and can be utilized to determine which entities are eligible to receive assignment of Corps members who are participating in the NHSC Scholarship Program based on the threshold HPSA score set forth below. Please note that entities on this list may or may not have current job opportunities for NHSC scholars. Further, not all vacancies associated with sites on the list described below will be for Corps members, but could be for NHSC Scholarship Program participants serving their obligation through the Private Practice Option.

Eligible HPSAs and Entities

To be eligible to receive assignment of Corps personnel, entities must: (1) Have a current HPSA status of "designated" by the Office of Shortage Designation, Bureau of Health Professions, HRSA; (2) not deny requested health care services, or discriminate in the provision of services to an individual because the individual is unable to pay for the services or because payment for the services would be made under Medicare, Medicaid, or the Children's Health Insurance Program (CHIP); (3) enter into an agreement with the State agency that administers Medicaid and CHIP, accept assignment under Medicare, see all patients regardless of their ability to pay and post such policy, and use and post a discounted fee plan; and (4) be determined by the Secretary to have (a) A need and demand for health manpower in the area; (b)

appropriately and efficiently used Corps members assigned to the entity in the past; (c) general community support for the assignment of Corps members; (d) made unsuccessful efforts to recruit; (e) a reasonable prospect for sound fiscal management by the entity with respect to Corps members assigned there; and (f) demonstrated a willingness to support and facilitate mentorship, professional development, and training opportunities for Corps members. Priority in approving applications for assignment of Corps members goes to sites that (1) Provide primary medical care, mental health, and/or oral health services to a primary medical care, mental health, or dental HPSA of greatest shortage, respectively; (2) are part of a system of care that provides a continuum of services, including comprehensive primary health care and appropriate referrals or arrangements for secondary and tertiary care; (3) have a documented record of sound fiscal management; and (4) will experience a negative impact on its capacity to provide primary health services if a Corps members is not assigned to the entity.

Entities that receive assignment of Corps personnel must assure that (1) The position will permit the full scope of practice and that the clinician meets the credentialing requirements of the State and site; and (2) the Corps member assigned to the entity is engaged in the requisite amount of clinical practice, as defined below, to meet his or her service obligation:

Full-Time Clinical Practice

"Full-time clinical practice" is defined as a minimum of 40 hours per week for at least 45 weeks per service year. The 40 hours per week may be compressed into no less than 4 work days per week, with no more than 12 hours of work to be performed in any 24-hour period. Time spent on-call does not count toward the full-time service obligation.

For all health professionals, except as noted below, at least 32 of the minimum 40 hours per week must be spent providing direct patient care or teaching in the outpatient ambulatory care setting(s) at the NHSC-approved service site(s) during normally scheduled office hours. The remaining 8 hours per week must be spent providing clinical services for patients or teaching in the approved practice site(s), providing clinical services in alternative settings as directed by the approved practice site(s), or performing practice-related administrative activities. Teaching activities at the approved service site shall not exceed 8 hours of the minimum 40 hours per week, unless the

teaching takes place in a HRSA-approved Teaching Health Center. Teaching activities in a Teaching Health Center shall not exceed 20 hours of the minimum 40 hours per week.

For obstetrician/gynecologists, certified nurse midwives (CNMs), family medicine physicians who practice obstetrics on a regular basis, providers of geriatric services, pediatric dentists, and behavioral/mental health providers, at least 21 of the minimum 40 hours per week must be spent providing direct patient care or teaching in the outpatient ambulatory care setting(s) at the NHSC-approved service site(s), during normally scheduled office hours. The remaining 19 hours per week must be spent providing clinical services for patients or teaching in the approved practice site(s), providing clinical services in alternative settings as directed by the approved practice site(s), or performing practice-related administrative activities. No more than 8 hours per week can be spent performing practice-related administrative activities. Teaching activities at the approved service site shall not exceed 8 hours of the minimum 40 hours per week, unless the teaching takes place in a HRSA-approved Teaching Health Center. Teaching activities in a Teaching Health Center shall not exceed 20 hours of the minimum 40 hours per week.

Half-Time Clinical Practice

“Half-time clinical practice” is defined as a minimum of 20 hours per week (not to exceed 39 hours per week), for at least 45 weeks per service year. The 20 hours per week may be compressed into no less than 2 work days per week, with no more than 12 hours of work to be performed in any 24-hour period. Time spent on-call does not count toward the half-time service obligation.

For all health professionals, except as noted below, at least 16 of the minimum 20 hours per week must be spent providing direct patient care in the outpatient ambulatory care setting(s) at the NHSC-approved service site(s), during normally scheduled office hours. The remaining 4 hours per week must be spent providing clinical services for patients or teaching in the approved practice site(s), providing clinical services in alternative settings as directed by the approved practice site(s), or performing practice-related administrative activities. Teaching and practice-related administrative activities shall not exceed a total of 4 hours of the minimum 20 hours per week.

For obstetrician/gynecologists, certified nurse midwives (CNMs),

family medicine physicians who practice obstetrics on a regular basis, providers of geriatric services, pediatric dentists, and behavioral/mental health providers, at least 11 of the minimum 20 hours per week must be spent providing direct patient care in the outpatient ambulatory care setting(s) at the NHSC-approved service site(s), during normally scheduled office hours. The remaining 9 hours per week must be spent providing clinical services for patients or teaching in the approved practice site(s), providing clinical services in alternative settings as directed by the approved practice site(s), or performing practice-related administrative activities. Teaching and practice-related administrative activities shall not exceed 4 hours of the minimum 20 hours per week. Half-time clinical service is not an option for scholars serving their obligation through the Private Practice Option.

In addition to utilizing NHSC assignees in accordance with their full-time or half-time service obligation (as defined above), sites receiving assignment of Corps personnel are expected to (1) Report to the NHSC all absences, including those in excess of the authorized number of days (up to 35 full-time days per service year in the case of full-time service and up to 35 half-time days per service year in the case of half-time service); (2) report to the NHSC any change in the status of an NHSC clinician at the site; (3) provide the time and leave records, schedules, and any related personnel documents for NHSC assignees (including documentation, if applicable, of the reason(s) for the termination of an NHSC clinician's employment at the site prior to his or her obligated service end date); and (4) submit an NHSC Site Survey. The survey allows the site to assess the age, sex, race/ethnicity of, and provider encounter records for, its user population. The survey is site specific. Providers fulfilling NHSC commitments are assigned to a specific site or, in some cases, more than one site. The scope of activity to be reported in the survey includes all activity at the site(s) to which the Corps member is assigned.

Evaluation and Selection Process

In order for a site to be eligible for placement of NHSC personnel, it must be approved by the NHSC following the site's submission of a Site Application. The Site Application approval is good for a period of 3 years from the date of approval.

In approving applications for the assignment of Corps members, the Secretary shall give priority to any such

application that is made regarding the provision of primary health services to a HPSA with the greatest shortage. For the program year July 1, 2011, through June 30, 2012, HPSAs of greatest shortage for determination of priority for assignment of NHSC scholarship-obligated Corps personnel will be defined as follows: (1) Primary medical care HPSAs with scores of 16 and above are authorized for the assignment of NHSC scholarship recipients who are primary care physicians, family nurse practitioners (NPs), physician assistants (PAs) or CNMs; (2) mental health HPSAs with scores of 16 and above are authorized for the assignment of NHSC scholarship recipients who are psychiatrists or mental health nurse practitioners; and (3) dental HPSAs with scores of 16 and above are authorized for the assignment of NHSC scholarship recipients who are dentists. The NHSC has determined that a minimum HPSA score of 16 for all eligible clinicians will enable it to meet its statutory obligation to identify a number of entities eligible for placement at least equal to, but not greater than, twice the number of NHSC scholars available to serve in the 2011–2012 placement cycle.

The number of new NHSC placements through the Scholarship Program allowed at any one site is limited to one (1) Of the following provider types: Physician (MD/DO) other than psychiatrist, NP, PA, CNM, dentist, or psychiatrist. The NHSC will consider requests for up to two (2) scholar placements at any one site on a case by case basis. Factors that are taken into consideration include community need, as measured by demand for services, patient outcomes and other similar factors. Sites wishing to request an additional scholar must complete an Additional Scholar Request form available at <http://nhsc.hrsa.gov/scholarship/pdf/additionalscholarrequestform.pdf>.

Application Requests, Dates and Address

The list of HPSAs and entities that are eligible to receive priority for the placement of Corps personnel may be updated periodically. Entities that no longer meet eligibility criteria, including those sites whose 3-year approval as an NHSC service site has lapsed or whose HPSA designation has been withdrawn or proposed for withdrawal, will be removed from the priority listing. New entities interested in being added to the high priority list must submit a Site Application to the National Health Service Corps by visiting <http://nhsc.hrsa.gov/communities/apply.htm> to apply online. A searchable database

of HPSAs and their scores, by State and county, is posted at <http://hpsafind.hrsa.gov/>.

Additional Information

Entities wishing to provide additional data and information in support of their inclusion on the proposed list of HPSAs and entities that would receive priority in assignment of scholarship-obligated Corps members must do so in writing no later than September 1, 2011. This information should be submitted to: Sonya Bayone, Chief, Site Branch, Division of the National Health Service Corps, Bureau of Clinician Recruitment and Service, 5600 Fishers Lane, Room 8-37, Rockville, MD 20857. This information will be considered in preparing the final list of HPSAs and entities that are receiving priority for the assignment of scholarship-obligated Corps personnel.

The program is not subject to the provisions of Executive Order 12372, Intergovernmental Review of Federal Programs (as implemented through 45 CFR Part 100).

Dated: July 22, 2011.

Mary K. Wakefield,
Administrator.

[FR Doc. 2011-19505 Filed 8-1-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed collection; Comment Request; A Generic Submission for Theory Development and Validation (NCI)

SUMMARY: Under the provisions of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: A Generic Submission for Theory Development and Validation (NCI). *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* In order to carry out NCI's legislative mandate to conduct and support research with respect to the causes and prevention of cancer, it is beneficial for NCI, through initiatives in the Behavioral Research Program (BRP), to conduct and support behavioral research informed by and informing theory. Formative research in the area of theory development and validation would provide the basis for developing effective cancer prevention and control

strategies, allow for a better understanding of theoretical constructs that influence decisions and actions related to cancer, and ultimately contribute to reducing the U.S. cancer burden. Data collections that result from this generic clearance would inform and clarify the use of theory in BRP-supported initiatives and funding announcements. Specifically, this research would allow NCI to conduct research to: (1) Identify psychological, biobehavioral, demographic, and individual difference predictors of cancer prevention and control behaviors and outcomes; (2) Develop and refine integrative theories; (3) Identify and observe theoretical and innovative trends in cancer prevention and control research; and (4) Determine feasibility and usefulness of collaborative and multidisciplinary approaches to cancer prevention and control. *Frequency of Response:* Will be determined by each project. *Affected Public:* Individuals or households; Businesses or other for profit; Not-for-profit institutions; Federal Government; State, Local, or Tribal Government. *Type of Respondents:* Members of the public including, but not limited to, health professionals, physicians, and researchers. Table 1 outlines the estimated burden hours and cost required for a three-year approval of this generic submission.

TABLE 1—ESTIMATES OF BURDEN HOURS FOR THREE YEARS (GENERIC STUDY)

Type of respondents	Number of respondents	Frequency of response	Average time per response (minutes/hour)	Total burden hours
General Public	2,000	1	15/60 (0.25)	500
Physicians	6,000	1	30/60 (0.5)	3,000
Health Professionals	1,000	1	60/60 (1)	1,000
Researchers	1,000	1	90/60 (1.5)	1,500
Total	11,500			6,000

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the

collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Richard P. Moser, Ph.D., Science of Research and Technology Branch, Behavioral Research Program, Division of Cancer Control and Population Sciences, National Cancer Institute/NIH, 6130 Executive Blvd., Rockville, MD 20892,

call non-toll-free number 301-496-0273 or e-mail your request, including your address to: moserr@mail.nih.gov.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: July 22, 2011.

Vivian Horovitch-Kelley,
NCI Project Clearance Liaison, National Institutes of Health.

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